

Attorney Docket No.: **ABLE-0014**
Inventors: **Ormerod and Winfield**
Serial No.: **09/530,375**
Filing Date: **July 7, 2000**
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make and/or use the invention. The Examiner suggests that the recitation of "pharmacologically active analogue, derivative or pro-drug thereof" does not adequately describe the materials used and/or how to make said materials. To facilitate the prosecution of the case, applicants have amended claim 24, and by dependency claims 25-26 and 28-39 in an effort to further clarify the invention. Accordingly, withdrawal of this rejection is respectfully requested.

II. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 24-26 and 28-39 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Gans et al. (US Patent 5,648,389). The Examiner suggests that Gans et al. disclose a composition comprising erythromycin and caprylic acid that may include other therapeutic agents, that is topically applied, and that is used to treat dermatological conditions. Further, the Examiner suggests that although this patent does not specifically disclose the instant invention it would have been obvious for one of skill in the art to use the materials taught by Gans et al. and then select the materials of the claimed invention without undue experimentation. Applicants respectfully traverse this rejection.

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At the outset, Applicants have amended claim 24, to incorporate the limitations of now canceled claim 27 which was not rejected under 35 U.S.C. 103(a) in light of Gans et al. The amendment to claim 24, and by dependency claims 25-26 and 28-39, now recites that the immunosuppressive macrolide is sirolimus, FK506 or SDZ ASM 981. Support for this amendment can be found throughout the specification and especially at page 5, lines 2-10.

Gans et al. (US Patent 5,648,389) discloses compositions for the treatment of acne and other dermatological disorders. The composition taught comprises a dermatologically absorbable antimicrobial, antibiotic, antibacterial or antifungal agent, a dermatologically absorbable hydroxy acid and a dermatologically absorbable water soluble zinc compound, as well as a dermatologically acceptable carrier. Although erythromycin, a macrocyclic lactone antibiotic is taught by this patent, nowhere does the patent teach or suggest adding an immunosuppressive macrolide or a permeation modulator as claimed in the instant invention. In the present invention, the immunosuppressive macrolide is sirolimus, FK-506 or SDZ ASM 981. Nowhere is this limitation taught or suggested by Gans et al.

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To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly, the prior art cited fails to teach or suggest the limitations of the claims as amended, which claim a topical formulation for the treatment of a dermatological condition which comprises a macrocyclic lactone antibiotic, an *immunosuppressive macrolide* wherein the *macrolide is sirolimus, FK506 or SDZ ASM 981*, and a permeation modulator which are present in relative amounts such that when a therapeutic amount is applied to the skin a minimal systemic effect is produced. In addition, the patent fails to provide a motivation for one of skill to combine the three agents of the instant topical formulation, a macrocyclic lactone antibiotic, an *immunosuppressive macrolide* and a permeation modulator, as it fails to mention the use of either the *immunosuppressive macrolide* or the permeation modulator. Accordingly, withdrawal of this rejection is therefore respectfully requested.

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III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Respectfully submitted,

Jane Massey Licata

Jane Massey Licata
Registration No. 32,257

Date: December 28, 2001

Licata & Tyrrell
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

The claims have been amended as follows:

24. (amended) A topical formulation for the treatment of a dermatological condition which comprises a macrocyclic lactone antibiotic, an immunosuppressive macrolide ~~or a pharmacologically active analogue, derivative, or pro-drug thereof~~ wherein the macrolide is sirolimus, FK506 or SDZ ASM 981 and a permeation modulator which are present in relative amounts such that when a therapeutic amount is applied to the skin a minimal systemic effect is produced.